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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,121	09/20/2001	Paul A. Levine	A01P1016	4136

7590 05/06/2004

PACESETTER, INC.  
15900 Valley View Court  
Sylmar, CA 91392-9221

EXAMINER
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OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/961,121

Applicant(s)

LEVINE, PAUL A.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/20/04 (Amendment).  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.  
4a) Of the above claim(s) 41-55 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-40 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Restriction/ Election***

1. Newly submitted claims 41-55 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Independent claim 41 classifies sensing threshold based on rhythmical consistency and classifies sensed cardiac events based on proximity relative to the sensing threshold; Independent claim 45 increase sensitivity based on the number of PVCs; Independent claim 48 classifies based on the proximity of the sensitivity of the cardiac event; and Independent claim 52 classifies a sensed cardiac event based only on the proximity of the sensitivity of the cardiac event, hence differing from the originally presented claims.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Response to Amendment***

2. The Applicant's arguments filed 2/20/04 are convincing, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 103***

3. Claims 1-3, 5-15, 25-30, 32, 33, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Steiner et al. (US 5868680).

Mc Clure et al. teach a cardiac arrhythmia detection system for an implantable device that senses atrial and ventricular sinus events /rhythmic event and ectopic events/ arrhythmic events/ PVCs (abstract; figure 8; col. 1 @ 10-16 and 48-59; col. 6 @ 50-58; col. 12 @ 22-31; col. 19 @ 47-67). Sensing thresholds for the pre-amplifier (42) are automatically set (col. 5 @ 41-64; col. 14 @ 44-48; col. 22 @ 59-62) and calibration periodically repeated (col. 2 @ 17-35; col. 10 @ 14-20). The sensing thresholds and timing relationships of the intervals are stored (col. 7 @ 8-14; col.8 @ 29-32; col. 12 @ 32-67; col. 13 @ 36-45; col. 14 @ 3-17). Cardiac events are classified based on the proximity to thresholds (col. 10 @ 66 – col. 11 @ 16).

As to claims 2, 3, 7-10, 29, 30, 36 and 37, rhythmic consistency and lack of rhythmic consistency are determined (col. 10 @ 66 – col. 11 @ 16; col. 16 @ 5-7) by sampling two consecutive intervals (col. 16 @ 56-65).

As to claims 11-12, seventy five percent, read as seventy percent, of the baseline value is used to denote significant change (col. 6 @ 16-25) and sensitivity is adjusted based on ectopic event history (col. 8 @ 62 - col. 9 @ 37).

As discussed in the previous four paragraphs of this action, McClure et al. disclose the claimed invention except for the cardiac events being classified based on proximity to the previous average cycle length.

Steiner et al. teach signal processing using cardiac events being classified based on proximity to the previous average cycle length for the purpose optimizing data measurement.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cardiac events being classified based on proximity to the previous average cycle length in the McClure et al. system in order to automatically provide signal precision enabling optimum functioning of the implanted device (col. 15 @ 53-63).

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Steiner et al. (US 5868680) and further in view of Weinberg et al. (US 5476485). As discussed in paragraph 3 of this action, modified McClure et al. disclose the claimed invention except for maintaining a sensitivity setting of a first amplifier while adjusting a sensitivity setting of a second sense amplifier.

Weinberg et al. teach amplifier sensitivity adjustment using two amplifiers and maintaining a sensitivity setting of a first amplifier (32) while adjusting a sensitivity setting of a second sense amplifier (64) for the purpose discriminating between signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used two amplifiers and maintaining a sensitivity setting of a first amplifier while adjusting a sensitivity setting of a second sense amplifier in the modified McClure et al. system in order to automatically provide signal clarity enabling optimum functioning of the implanted device (col. 1 @ 7-13; col. 1 @ 61 – col. 2 @ 12; col. 6 @ 43-67).

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Steiner et al. (US 5868680) and further in view of Mann et al.

(US 5476485). As discussed in paragraph 3 of this action, modified McClure et al. disclose the claimed invention except for the data retrieved from the implanted device being displayed as a histogram.

Mann et al. teach data display using a histogram for the purpose of visually presenting cardiac data to the physician. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a histogram in the modified McClure et al. system in order to enable the physician to easily evaluate the cardiac activity and the effectiveness of treatment (abstract; col. 6 @ 27 – col. 7 @ 11; col. 25 @ 10-14).

6. Claim 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClure et al. (US 5560369) in view of Steiner et al. (US 5868680) and further in view of Schuelke et al. (US 6112119). As discussed in paragraph 3 of this action, modified McClure et al. discloses the claimed invention except for detecting a PVC based on the presence or absence of an atrial event (claims 17-18) where the average A-V interval is used to determine the sinus or ectopic nature of the event (claims 19-21), and determining and storing the A-V interval using a window (claims 22-24).

Schuelke et al. teach cardiac signal sensing using adjustment of the amplifier sensitivity/gain with the following methods: detecting a PVC based on the presence or absence of an atrial event where the average A-V interval is used to determine the sinus or ectopic nature of the event, and determining and storing the A-V interval using a window for the purpose of accurately interpreting the nature of the cardiac signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the following methods:

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detecting a PVC based on the presence or absence of an atrial event where the average A-V interval is used to determine the sinus or ectopic nature of the event, and determining and storing the A-V interval using a window in the modified McClure et al. system in order to avoid improper device settings for the particular patient and situation so the implantable cardiac device operates effectively (abstract; col. 3 @ 53-63; col. 4 @ 26-53; col. 8 @ 8-13; col. 9 @ 22-34; col. 11 @ 22-25; col. 19 @ 3-13; col. 26 @ 35-57; col. 27 @ 1-15; col. 31 @ 58-65; col. 34 @ 25-45; col. 44 @ 33-39).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist at telephone number (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*5/2/04*

*Angela D. Sykes*

**ANGELA D. SYKES  
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